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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,783

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Yuji Matsuzawa

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EXAMINER

LIU, SAMUEL W

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,783	Applicant(s) MATSUZAWA ET AL.	
	Examiner SAMUEL W. LIU	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 and 50-67 is/are pending in the application.
- 4a) Of the above claim(s) 2-44, 46-48, 50-54 and 56-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 45 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/9/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of claims

Claims 1-48 and 50-67 are pending.

The amendment filed 1/16/08 which amends claims 1, 45 and 55, adds claims 66-67, and cancels claim 49 has been entered. The applicants' request filed 1/16/08 for extension of time of two months has been entered. New claims 66-67 are drawn to a non-elected invention. Claims 2-44, 46-48, 50-54, and 56-65 remain withdrawn and claims 66-67 are withdrawn from further consideration by Examiner. Claims 1, 45 and 55 and the elected SEQ ID NO:2 are examined in this Office action.

Restriction/Restrictions

Applicants' response filed 1/16/08 requests examination of claims 1, 45, 55 and new claims 66-67 (page 19, last paragraph). Applicant's request is acknowledged, however, it is noted that claims 66-67 are drawn to a method of screening a compound comprising contacting a protein comprising SEQ ID NO:2 and determining binding of the test compound with said protein, whereas claims 1, 45 and 55 are drawn to an isolated protein. Here, the elected claims 1, 45 and 55 relate to claims 66-67 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case, the protein can be utilized in a materially different processes, e.g., producing an antibody that binds to the protein thereof. Thus, claims 66-67 and the elected invention of

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claims 1, 45 and 55 are patentably distinct from each other and are withdrawn from consideration as being drawn to a non-elected invention.

Information Disclosure Statement

The references: WO 01/57188, WO 01/00638, WO 01/64835, and WO 01/48192 cited in the IDS filed 8/9/05 have been considered by Examiner. A copy of the IDS filed on 8/9/05 is attached to the instant Office action.

Withdrawal of objection and rejections

- The objection of the specification is withdrawn in light of the amendment of the specification thereof.
- The rejection of claims 1, 45, 49 and 55 under 35 USC 112, second paragraph, is withdrawn in light of the amendment of claim 1, and cancellation of claim 49.
- The rejections of claims 1, 45, 49 and 55 under 35 USC 112, first paragraph (written description and scope enablement) are withdrawn in light of the amendment of claim 1, and cancellation of claim 49.
- The rejection of claims 1, 45, 49 and 55 under 35 USC 102(e) by Goddard et al. is withdrawn in light of the amendment of claim 1, and cancellation of claim 49.
- The rejection of claims 1 55 under 35 USC 103(a) by Wood et al. and Ali et al. is withdrawn in light of the amendment of claim 1, and cancellation of claim 49.

New-Claim Rejections - 35 USC § 101 (lack of utility)

35 U.S.C. §101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 1, 45 and 55 are rejected under 35 USC 101 because the claimed invention is not supported by either a well-established or disclosed specific and substantial credible utility.

For a utility to be “well-established” it must be specific, substantial and credible.

The protein of instant SEQ ID NO:2 is not supported by a specific asserted utility. The specification refers to the protein of SEQ ID NO:2 as “**SST20-14** (long form)” (see page 11, line 25) which is asserted to be a mouse white adipose tissue derived secretory protein (page 138, lines 15-18).

The specification asserts that the gene encoding “SST20-14” protein is specifically expressed in white fat tissue (page 56, lines 27-28).

The specification asserts that the “SST20-14” gene is decreased in expression at the time of fasting, and in response to stimulation of insulin resistance (page 56, lines 32-35), and further asserts that the excessive expression of said gene also suppresses differentiation of precursor adipocytes (page 37, lines 1-3).

The current invention is directed to the isolated protein comprising SEQ ID NO:2, i.e., “SST20-14”. The above-asserted specific gene expression of “SST20-14” in white fat tissue is not considered to be a specific utility of the “SST20-14” protein. This is because regulation of an mRNA transcribing a protein is not considered to be an intrinsic property of the protein thereof. It is well known in the art that gene expression can be potently regulated through modulating the promoter which controls the gene expression or the mRNA transcription thereof. Thus, the results of specific “gene expression” may not reflect the function and usefulness *per se* of the protein which is the product of said gene expression. The art teaches that the expression of leptin, a protein produced in adipose tissue, is regulated by several extrinsic factors which are unrelated

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to the leptin structure and function (see page 768, left column, last two lines, Friedman et al. (1998) *Nature*, 395, 763-770).

The specification asserts that the “SST20-14” protein had a motif which can bind to lipid of lipoprotein (page 147, lines 13-14). Neither instant specification nor the art in the relative field provides factual indicia to show this motif and/or the binding of this motif with other biological factors. The specification is completely silent in teaching the structural feature of this "motif" so as to compare it with motifs of proteins with known functions.

Many proteins or molecules can bind to lipid of a “lipoprotein”, e.g., albumin which binds a wide variety of endogenous substances and drugs also is able to bind the fatty acid chain of acylated insulin (which here is considered to be a “lipoprotein”) (see abstract, Kurtzhals et al. (1995) *Biochem. J.*, 312, 725-731). This indicates that binding to lipid moiety of a lipoprotein cannot be considered specific. Therefore, the above asserted utility of the “SST20-14” protein is a utility which would apply to every member of a general class of molecules, such as collection of proteins, but is only potential with respect to said protein. Because of this, such a utility is not specific and does not constitute a “well-established” utility.

The claimed protein of SEQ ID NO:2 is not supported by a substantial utility. The specification as filed does not disclose or provide any factual evidence that points to an activity having real world use (biological role or/and therapeutic role) of said polypeptide. The specification does not teach direct use of the claimed protein to treat a condition or disease or applied to a biological event having substantial utility. The specification contemplates that “SST20-14” gene expression is decreased in response to stimulation of insulin resistance (page 56, lines 32-35). However, the specification teaches nothing nor provides factual indicia as to

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whether “SST20-14” protein *per se*, but not DNA thereof, is applicable to treatment of insulin resistance. The art in the relative fields does not teach in this regard either. It is well-known in the art that the levels of mRNA do not necessarily correlate with the levels of the corresponding protein. See, *e.g.*, Chen et al. (*Mol. Cell Prot.* 1:304-313, 2002), which teaches “[t]he use of mRNA expression patterns by themselves, however is insufficient for understanding the expression of protein products, as additional post-transcriptional mechanisms, including protein translation, post-translational modification, and degradation, may influence the level of a protein present in a given cell or tissue” (p. 304, right column). Furthermore, the specification does not disclose the core sequence(s) or domain(s) critical for biological function of “SST20-14”. Hence, one skilled in the art is unable to compare “SST20-14” with known proteins that have real world utilities in order to practice the claimed invention.

The above-discussed asserted utilities constitute carrying out further research upon the protein being in hand to identify or reasonably confirm a “real world” context of use (*e.g.*, diagnosing or/and treating a particular disease state). See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). The specification must teach a skilled artisan how to use what is claimed and not merely provide a blueprint for further experimentation in order for an artisan to identify a use for the claimed invention. As stated in *Brenner v. Manson*, 383 U.S. 519 535-536, 148 USPQ 689,696 (1966), “[a] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion”. Thus, the test for substantial utility is not considered to be met; and therefore, the current application lacks substantial utility.

Claims 45 and 55 are directed to a composition and a kit comprising the protein of SEQ ID NO:2 or “SST20-14”, respectively. Because the protein lacks specific and substantial utility

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discussed above, the composition of claim 45 and the kit of claim 55 also do not have a “well-established” utility. .

New-Claim Rejections - 35 USC § 112, the first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement rejection

Claims 1, 45 and 55 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

This rejection stands for the reasons set forth in the foregoing statement of the grounds of rejection under 35 U.S.C. 101.

The specification fails to teach that the disclosed protein comprising instant SEQW ID NO:2, i.e., “SST20-14” has useful biological activity which relates to the above-discussed specific and substantial utility. Accordingly, the composition (claim 45) and the kit (claim 55) comprising the protein thereof have no therapeutic or biological applications. Thus, one skilled in the art is unable to use the claimed protein, or/and the composition comprising the protein for modulating differentiation of adipocytes, or/and the kit comprising the protein for screening a compound which has specific affinity for the protein thereof.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

/Samuel W Liu/Ph.D.

Examiner, Art Unit 1656

April 3, 2008

/David J. Steadman/

Primary Examiner, Art Unit 1656